CANDELA

K 063074

510(k) Summary

DEC 27 2006

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.92.

Submitter Information

Company Name:	Candela Corporation
Company Address:	530 Boston Post Road Wayland, MA 01778
Company Phone:	508-358-7400
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Contact Person:	Mr. Jeffrey Roberts Manager, Regulatory Affairs
Date summary Prepared:	10/05/06

Device Identification

Device Trade/Proprietary Name:	Candela 3630 Laser System
Common Name:	Medical Laser System
Classification Name:	Laser Surgical Instrument, for use in General and Plastic Surgery and Dermatology
Classification Regulation:	21 CFR § 878.4810
Device Classification:	II

Identification of Predicate Device

Predicate Device(s):	Candela GentleYAG Family of Laser Systems, K033172 Candela GentleLASE Family of Laser Systems, K024371 Candela GentleLASE Family of Laser Systems, K024335 Candela GentleLASE Family of Laser Systems, K024260 Cynosure Apogee Elite Laser, K034030

Device Description

The Candela 3630 Laser System contains two separate laser heads (Alexandrite and Nd:YAG) which produce laser light outputs of 755 nm and 1064 nm. The outputs of each laser head are optically combined on the laser rail so that their beam paths are identical as they exit the laser system. This allows the use of a single delivery system which can output either 755 nm, 1064 nm wavelengths.

Each laser head contains the appropriate solid state laser rod and high intensity xenon flashlamps to excite the laser medium. The laser heads are water cooled with a self contained circulating water system that includes a water to air heat exchanger so the system can be fully air-cooled. The temperature of the laser heads are regulated by the circulation of distilled water at a

controlled temperature. A high voltage power supply is used to charge a storage capacitor which provides energy to the flashlamps. An IGBT (high voltage switch) is used to discharge the capacitor through the flashlamp. Each laser head has its own dedicated IGBT switch which is how the system controls which wavelength is produced. The resulting flash of the flashlamp excites the laser rod which causes emission of a pulse of laser energy.

The Candela 3630 Laser System delivers laser energy with various pulse durations from 0.25 milliseconds to 300 milliseconds (See attached specification 9914-92-0400 for further details). The output of this laser is delivered to the area of treatment by means of a lens coupled user replaceable optical fiber with a treatment handpiece attached to its distal end. A trigger switch (fingerswitch or footswitch) is used to control the delivery of laser pulses. The user may choose to deliver a single pulse each time the trigger switch is depressed, or pulses may be delivered repetitively as long as the switch is depressed, at repetition rates up to 10 pulses per second (depending on the chosen pulse duration).

A microprocessor based system controller is used to monitor and direct all system functions. Users of the laser select parameters such as desired energy density (fluence) level and repetition rate and monitor operation via a touch screen and display panel. The touch screen panel can also be used to enable or disable the triggering of the laser, to initiate the calibration feature and to obtain feedback from the system, such as the number of pulses delivered or spot size selected. The Candela 3630 Laser System supports spot sizes from 1.5 to 18 mm.

Description of Intended Use

755nm

The Candela 3630 Laser System is indicated for the temporary hair reduction. Stable long-term or permanent hair reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing after a treatment regime. On all skin types (Fitzpatrick I-IV) including tanned skin.

Treatment of benign pigmented lesions. Treatment of wrinkles.

1064nm

The Candela 3630 Laser System is indicated for the removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The lasers are indicted on all skin types Fitzpatrick I-VI including tanned skin. Photocoagulation and hemostasis of pigmented and vascular lesions such as but not limited to port wine stains, hemoangioma, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. Coagulation and hemostasis of soft tissue. Benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue-black tattoos) and plaques.

The laser is indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
The laser is also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
Treatment of wrinkles.

Rationale for Substantial Equivalence

The Candela 3630 Laser System has the same intended use, utilizes similar functional features (including power output, spot size, repetition rate, energy, and fluence) and matches key design aspects (including wavelength, light generation medium, power supply, cooling and controls system) , as the predicate devices.

The Candela 3630 Laser System shares similar methods of assembly, method of operation, and intended uses, and therefore is substantially equivalent to the currently legally marketed Candela GentleYAG Family of Laser Systems, K033172, Candela GentleLASE Family of Laser Systems, K024371, K024335, K024260, and Cynosure Apogee Elite Laser, K034030 predicate devices.

Safety and Effectiveness Information

The Candela 3630 Laser System is substantial equivalent to the currently legally marketed Candela GentleYAG Family of Laser Systems, K033172, Candela GentleLASE Family of Laser Systems, K024371, K024335, K024260, and Cynosure Apogee Elite Laser, K034030 predicate devices in intended use and technological features and therefore the risks and benefits are comparable to the predicate devices.

We therefore believe that there are no new questions of safety or effectiveness raised by the introduction of the Candela 3630 Laser System.

Conclusion

Base on the similarities in indications for use, design features, and functional features the Candela 3630 Laser System has been shown to be substantially equivalent to the current legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Candela Corporation
% Mr. Jeffrey Roberts
Manager, Regulatory Affairs
530 Boston Post Road
Wayland, Massachusetts 01778

DEC 27 2006

Re: K063074
Trade/Device Name: Candela 3630 Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: October 5, 2006
Received: October 10, 2006

Dear Mr. Roberts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063074

Device Name: Candela 3630 Laser System

Indications for Use:

755nm

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Barbara Buchman

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K063074

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchner

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063074